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10/759,741	01/15/2004	William A. McMillan	020048-003121US	6891

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TOWNSEND AND TOWNSEND AND CREW, LLP  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO, CA 94111-3834

EXAMINER

REDDING, DAVID A

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/759,741

Applicant(s)

MCMILLAN ET AL.

Examiner

David A Redding

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 83-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Cancellation of the non-elected claims 1-82 is acknowledged. Claims 83-85 are pending.
2. Applicant's arguments filed 4/30/03 have been fully considered but they are not persuasive.

***Specification***

3. The amendment filed 8/13/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In claims 83 and 84, the claims define a "micro-sonicator" and "micro-fluidic system". The examiner has reviewed the specification and there is no support in the specification for such embodiments.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 83, and 84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 83 and 84, the claims define a "micro-sonicator" and "micro-fluidic system". The examiner has reviewed the specification and there is no support in the specification for such embodiments. A review of the specification reveals that there is no support in the specification for such an embodiment.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 83-85 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,100,084 (Miles et al.).

Claims 83-84 have priority only to the filing date (5/30/2000) of the instant application. Applicant asserts priority to provisional application 60/136,703, filing date 5/28/1999.

Art Unit: 1744

However, a review of the specification of the provisional document reveals that claims 83-85 are not supported by the disclosure within the provisional document. Actually, the provisional document is directed away from a "micro-sonicator" and designed to handle larger sample sizes (col.2, lines 21-col.3, line 26). Further, the provisional document does not disclose a membrane, rather specifies a gasket. Accordingly, the priority of claims 83-85 is the filing date of the instant application, which qualifies U.S. Patent 6,100,084 as prior art. As stated in applicants response filed 7/13/01, claims 1-14,17, and 18 correspond to claims 83-85, thus anticipating claims 83-85.

Claims 84 and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 4,963,498 (Hillman et al.).

Figures 1a,1b,2a,2b show a microfluidic device comprising chambers 62,60 and 58. The device is intended for performing agglutination assays on cells (abstract). The device can be used for assaying blood which is considered to be equivalent to the claimed "transmission media" (col.4, lines 17-32). Covering the chambers are a top surface (52, figure 2b) which is considered to read on the claimed "membrane". The reference further discloses that it is routine to apply an external vibrator or ultrasonic transducers to the device (col.16, lines 25-34).

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1744

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 84 and 85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 10/006,848 in view of USP 5,856,174. Claim 1 in the '848 application defines a device for lysing comprising, in part, a lysing chamber and an ultrasonic transducer which is coupled to the wall of the lysing chamber.

The claim does not specify a transmission media. The '174 patent discloses a similar lysing chamber in which is added deionized water as a transmission media (example #1). Accordingly, it would be obvious to one skilled in the art to include the transmission media disclosed in the US patent into the device claimed in the '848 application, especially in view of the fact that both devices are used for lysing.

This is a provisional obviousness-type double patenting rejection.

10. Claims 84 and 85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 of US patent 6,664,104 in view of USP 5,856,174 ('174). Claim 3 in the '104 patent defines a device for lysing comprising, in part, a lysing chamber and an ultrasonic transducer which is coupled to the wall of the lysing chamber. The claim does not specify a transmission media. The '174 patent discloses a similar lysing chamber in which is added deionized water as a transmission media (example #1).

Art Unit: 1744

Accordingly, it would be obvious to one skilled in the art to include the transmission media disclosed in the US patent into the device claimed in the '104 patent, especially in view of the fact that both devices are used for lysing.

This is a provisional obviousness-type double patenting rejection.

11. Claims 83-85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/208,976 in view of GB 938,163. It would have been obvious to one skilled in the art to include beads into the chamber of the instant application in view of the known advantage in assisting in the lysing of cells.

This is a provisional obviousness-type double patenting rejection.

12. Claims 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,168,948 B1 (Anderson et al.) in view of USP 5,856,174 ('174).

The Anderson et al. patent discloses an embodiment (figure 28) for controlling the degree of lyses.

The device comprises an injected molded chamber 3006 (cavity) which is covered by a polymeric base 3004, which is considered to be equivalent to the claimed membrane. The base may be in the form of adhesive tape or thin film (col.42, line 28-30). The device further comprises a piezoelectric crystal 3002 coupled to a thinned wall 3020 of the base 3004 via a filled balloon. In use, the piezoelectric crystal 3002 generates acoustic energy that is directed into the chamber to cause cells within the chamber to lyse (col.42, lines 4-30).

Art Unit: 1744

In example #1 of the Lipshutz et al. patent water is used as an ultrasonic transmission media for lysing cells in a similar device to that disclosed in the Anderson et al. patent. Accordingly, it would have been obvious to one skilled in the art to use the transmission media disclosed in the Lipshutz et al. patent in the device (figure 28) described in the Anderson et al. patent in view the disclosed use of both devices for cell lysis using ultrasonic energy.

***Response to Arguments Filed 4/30/2003 in application 09/584,327***

13. **Applicants arguments concerning 35 U.S.C. 112 (1<sup>st</sup> paragraph) – New Matter**

Applicant asserts in pages 4 thru 5 of the response that both the provisional document and the specification of the instant application provides support for the term “micro-sonicator”. The examiner disagrees. The support cited on pages 23,39 of the provisional document merely describes the **sonication** steps and nowhere is the term “micro-sonicator” used. Pages 7 and 34 the terms “microprocessors”, “microcontrollers”, are cited by applicant as support. Yet these terms describe the controls for the device and not the structure which performs the sonication step.

Alleged support in the specification cited by applicant for “micro-sonicator” is equally flawed. None of the citations expressedly or imply a “micro-sonicator”. The support of page 28, lines 17-31 cited by applicant is directed to **reaction vessel 40** not the chamber in the lysing chamber 86 in which ultrasound is used. The **reaction vessel 40** is not a component of the lysing chamber 86. It is a separate element which makes of applicants “cartridge” invention.



Art Unit: 1744

Applicant is directed to page 15, line 30 thru page 23, line 25. The evidence cited by applicant on page 104 of the provisional document is a general description of all of the chambers of the cartridge 20 with no specific reference to the lysing chamber 86 in which actual sonication of the sample occurs. The support cited on page 42 of the provisional document describing microliter volumes is directed to volumes contained in the **reaction chamber** 40 and not the lysing chamber.

Applicant's cited support for the term "microfluidic" is also found lacking. The support cited on page 5 of the provisional application is to an article by Anderson et al. and not a reference to applicant's claimed invention. Similarly, the support cited on page 9 of the instant specification describes fluidic systems, not micro-fluidic.

The support cited for the terms "ultrasonic transmission media" and "ultrasonic excitation of the transmission media" is persuasive. Specifically, page 6, lines 3-13 of the provisional document cited by applicant. Since the instant application, at the time of filing, incorporated by reference the contents of the provisional document, applicant has sufficient support for the terms "ultrasonic excitation of the transmission media". The rejection has been withdrawn.

**Applicants arguments concerning the 35 U.S.C. 102 rejection**

Applicant argues that the size of the lysing chamber in the instant application handles volumes smaller than the micro-sonicator in Miles et al. and inherently than has support for the added terms. The examiner disagrees. The chamber applicant is

Art Unit: 1744

describing is the **reaction vessel** 40 and not the chamber in which sonication occurs, chamber 86.

Accordingly, applicant does not have support for the terms "micro-sonicator" or "micro-fluidic" and does not receive benefit of the filing date of the provisional document . The effective date for the claims is the filing date of the instant application, 30 May 2000 , qualifying US patent 6,100,084 as prior art under 35 U.S.C. 102 (e).

**Applicant's arguments concerning the Double Patenting rejections**

The Terminal Disclaimers for US patents 6,440,725; 6,391,541; 6,431,476 are acknowledged and the rejections in view of those patents withdrawn. The provisional obvious-type double patenting rejections will remain until all other rejections of the claims are overcome.

The declaration filed on 4/30/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the US patent 6,100,084 reference. The evidence provided is illegible and therefore is not sufficient to show that applicant had reduced to practice the claimed invention prior to the filing date of USP 6,100,084.

***Information Disclosure Statement***

14. The information disclosure statement filed May 3, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all

Art Unit: 1744

other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Conclusion***

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Redding whose telephone number is 703-308-3910. The examiner can normally be reached on M,T,Th,Fr, 7:30-6:00pm.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Art Unit: 1744

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

A handwritten signature in black ink, appearing to read "David A. Redding". The signature is fluid and cursive, with the first name "David" and last name "Redding" clearly distinguishable.

David A Redding  
Primary Examiner  
Art Unit 1744

D.A.R.  
March 17, 2005